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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1633	6

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,592	EMERSON, BEVERLY M.	
	Examiner	Art Unit	
	Brian Whiteman	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Non-Final Rejection

Priority

Priority to provisional application 60/181,864 filed on 2/11/2000 is acknowledged.

Information Disclosure Statement

The information disclosure filed on July 5, 2001 does not fully comply with the requirements of 37 CFR 1.98 because: applicant does not properly cite a journal article listed on the 1449. The author's name (Muchardt) on page 3 is misspelled.

The examiner has considered all of the references, but in order to have the article listed above initialed and dated on the 1449, a new 1449 properly citing the article must be filed with the response to this office action. Failure to comply with this notice will result in the above mentioned information disclosure statement being placed in the application filed with the non-complying information not being considered. See 37 CFR 1.97(i).

Claim Objections

Claim 11 is objected to because of the following informalities: a comma should be inserted after the term NRUD on line 31, page 40. Appropriate correction is required.

Claims 1-37 are pending for examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-37 are rejected under 35 U.S.C. 101 because the claimed invention is lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well-established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS: repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" – Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, office personnel must determine if the assertion of utility is credible (i.e. whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based in inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific utility" – a utility that is *specific* to the subject matter claimed. This contrast with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what conditions can be diagnosed.

"Substantial utility" – a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material, which has a stated correlation to a predisposition to the onset of a particular disease condition, would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying our further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic Research such as studying the properties of the claimed produce itself or the mechanisms in which the material is in involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. 101. This analysis should of course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" – a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone, or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a non-specific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this were the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight, any carbon containing molecule would have a "well established utility" as a fuel since it can by burned; and any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

[See also the MPEP at 2107 –2107.02].

On pages 26-31 of the disclosure, the specification displays prophetical working examples encompassing a pharmaceutical screening protocol. More specifically, the disclosure states, "The assays can also be used to screen for drugs that modulate the interaction between chromatin remodeling complex and a domain within a protein. The claimed invention has a

credible utility since one skilled in the art would accept that the recited invention is currently available for use as claimed. However, the claimed invention lacks a substantial utility because a genus of compounds that modulate the interaction of a subunit of a chromatin remodeling complex and a domain within a protein would require further research to identify and reasonably confirm a "real world" use. The specification fails to provide any compound other than generic terms (e.g. antibodies, DNA, proteins, organic compounds, etc.), which could be used in any method of altering remodeling of chromatin in a cell or a method of altering activation of transcription in a cell. In addition, the claimed invention lacks a "well established utility" since the possibility of any member of a general class of materials, such as proteins or DNA could be used in the claimed invention.

Claims 1-37 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-37, as best understood, are readable on a genus of a compound that modulates the interaction of a subunit of a chromatin remodeling complex and a domain within a protein, wherein the genus of the compound is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are

rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-30 and 35-37, as best understood, are readable on a genus of a method of remodeling chromatin or altering activation of transcription in a cell comprising administering to the cell a compound that modulates the interaction of a subunit of a chromatin remodeling complex and a domain within a protein, wherein the genus of the method is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates a compound that compound that modulates the interaction of a subunit of a chromatin remodeling complex and a domain within a protein that can be used in a method of altering activation of transcription or altering remodeling of chromatin in a cell. The specification contemplates several different genuses of compounds (e.g. antibodies, polypeptides, steroids, organic compounds, etc.). See pages 12-13.

However, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of compounds, method of altering activation of transcription, or

method of altering remodeling of chromatin as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of compounds and methods that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient to support the present claimed invention directed to a genus of a compound that modulates the interaction of a subunit of a chromatin remodeling complex and a domain within a protein or a method of altering remodeling of chromatin or a method of altering transcription. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming unspecified compounds and methods that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed compound and methods that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods

disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possession of a genus of a compound), particularly in view of the reasons set forth above, one skilled in the art would not have known how to use and make the claimed invention so that it would operate as intended, e.g. modulated interaction of a subunit of a chromatin remodeling complex and a domain within a protein.

Specifically, the specification teaches in vitro experiments that demonstrate how mammalian chromatin remodeling complexes regulate transcription. More specifically, the specification specifically teaches how SWI/SNF regulates transcription from chromatin-assembled genes in a factor specific manner in vitro (Example 1, pages 18-19). Furthermore, the

specification teaches that SWI/SNF selectively functions with several zinc finger DNA-binding proteins to remodel chromatin and activate transcription in vitro (pages 19-21). Example 2, a pharmaceutical screening protocol in contemplated (pages 26-29). Example 3, the specification teaches that activation of repressed genes by facilitated protein binding through targeted chromatin remodeling by zinc finger protein motifs and SWI/SNF (pages 29-30). Example 4, the specification uses an assay to display that either β-globin gene with SWI/SNF + EKLF or the gamma-globin gene are differently activated with a novel protein complex and this assay can be used as a high-throughput drug screening assay (page 30). Example 5, the specification teaches an in vitro assay has been developed that reproduced p-53 dependent activation of the p21 cell cycle inhibitor gene and this assay can be used for high-throughput screening of drugs that enhance or interfere with protein interaction (pages 31-32).

The specification teaches how particular proteins interact with one another in an in vitro binding assays. However, the specification lacks sufficient guidance for how one skilled in the art could reasonably extrapolate from in vitro protein binding assays to compounds that modulate an interaction of a subunit of a chromatin remodeling complex and a domain within a protein. In view of the rejections under written description and the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Even if the applicant is able to overcome the 101 and written description issues with making and/or using a method or a compound that modulates the interaction between chromatin remodeling complex and a domain within a protein, the claimed invention encompasses an ex vivo or an in vivo cell used in a method of altering remodeling of chromatin or altering

activation of transcription and since the specification does not provide sufficient guidance for the starting material, which is a compound, it would take one skilled in the art an undue amount of experimentation to make and/or use any in vivo or ex vivo method of altering activation of transcription or remodeling chromatin.

Furthermore, and with respect to claims (e.g. claims 31-34) directed to any pharmaceutical agent useful for gene therapy and directed to any in vivo method of altering remodeling of chromatin in a cell; the state of the art in 1998, exemplified Anderson et al., *Nature*, Vol. 392, pp. 25-30, April 1998, displays major consideration for any gene transfer or any DNA therapy protocol involve issues that include:

1) The type of vector and amount of DNA constructs to be administered,

2) The route and time course of administration, the sites of administration, and successful uptake of the claimed DNA at the target site;

3) The trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA product, the amount and stability of the protein produced, and

4) What amount of the expressed proteins considered to be therapeutically effective for a DNA therapy method (Anderson, *Nature*, Vol. 392, pp. 25-30, April 1998).

In addition, all of these issues differ dramatically based on the specific vector used, the route of administration, the animal being treated, therapeutically effective amount of the DNA, and the disease being treated.

Anderson teaches that gene therapy is a powerful new technology that still requires several years before it will make a noticeable impact on the treatment of disease, and that several

major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered (pp. 25-30).

Anderson further teaches that the reason for the low efficiency of gene transfer and expression in human patients is that we still lack the basis understanding of how vectors should be constructed what regulatory sequences are appropriated for which cell types (page 30, column 1, last paragraph). Furthermore, Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2). Thus, gene therapy is considered unpredictable.

As stated above, the specification lacks sufficient guidance for any compound that could be used in a method of gene therapy for treating any disease that is associated with modulating the interaction of a subunit of a chromatin remodeling complex and a domain within a protein. Since the specification does not teach how to make and/or use any compound, one skilled in the art would not known how to therapeutically treat any mammal with a disease, wherein a therapeutic compound would modulate (increase/decrease) an interaction of a subunit of a chromatin remodeling complex and a domain within a protein. Thus, in view of the art of record and lack of sufficient guidance provided by the specification, it would require one skilled in the art an undue amount of experimentation to determine how to make and/or use an pharmaceutical agent for gene therapy comprising a compound that modulates the interaction of a subunit of a chromatin remodeling complex and a domain within a protein.

Furthermore, claims 1-37 read on modulating an interaction of a subunit of a chromatin remodeling complex and a domain within a protein, and the state of the art and the specification lacks sufficient guidance for one skilled in the art to use any compound to modulate the degree of interaction between a subunit of a chromatin remodeling complex and a domain within a protein. The term modulate is broad and encompasses any degree of regulation of the two components listed above. Therefore, it would take one skilled in the art an undue amount of experimentation to make and/or use any compound that can modulate an interaction between to components since the specification lacks sufficient guidance for what degree of interaction is required and how to control the modulation.

Even if the applicant is able to overcome the enablement issues listed above for making and/or using a method of altering remodeling of chromatin in a cell or using a compound in the method, the claimed invention encompasses a human chromatin remodeling complex, the specification lacks sufficient guidance for one skilled in the art to make and/or use any method of altering remodeling a chromatin in a cell comprising administering to the cell a compound that modulates an interaction of a subunit of a human chromatin remodeling complex and a domain within a protein. In view of the lack of sufficient guidance provided by the specification and the state of the art, it would take one skilled in the art an undue amount of experimentation to make and/or use a human chromatin remodeling complex because the specification does not provide sufficient guidance for several areas of concern that encompass: what compound could be used, what route of administration would results in a therapeutic effect being observed in an in vivo method of therapy for altering remodeling chromatin in a cell, what vector could be used in either method to modulate the interaction of the components listed above. Thus, in view of the

concerns listed above the specification is not enabled for using any human chromatin in a method of altering remodeling a chromatin in a cell.

In addition, with respect to claim 30, the specification does not provide sufficient guidance for how to make and/or use an in vitro system to modulate transcription comprising a subunit of a chromatin remodeling complex and a domain within a protein. The only guidance provided by the specification is the contemplation that to employ the in vitro system as contemplated by the claimed invention a compound is required to modulate the transcription. Thus, it would require an undue amount of experimentation for one skilled in the art to make and/or use an in vitro system to modulate transcription comprising a subunit of a chromatin remodeling complex and a domain within a protein.

As a result, it is not apparent how one skilled in the art determines, without undue experimentation, which of the claimed pharmaceutical agents generate a therapeutic effect, how is it apparent as to how one skilled in the art, without any undue experimentation, practices any therapy method as contemplated by the claims, particularly given the unpredictability of nucleic acid therapy as a whole and/or the doubts expressed in the art of record.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made lack sufficient guidance and/or evidence to reasonably enable the claimed invention. Given that there is no representative number of compounds that could be used in any method to modulate any interaction of a subunit of a chromatin remodeling complex and a domain within a protein. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. In addition, since the

disclosure does not provide sufficient guidance for what pharmaceutical composition comprising a compound for use in a method of gene therapy wherein any carrier is employed to correct a disease or a medical condition in any mammal was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to a gene therapy effect, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicant's disclosure and the unpredictability of gene therapy.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 7, 16, 20, 28, 30, 32, and 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite as to what the phrase "altering remodeling of chromatin" is intended to be encompassed with regard to interaction with a subunit of a chromatin of a chromatin remodeling complex. While a chromatin structural change can occur on several levels, it is not apparent what is the end product of altering remodeling of chromatin. In the art of chromatin, a change is usually defined by a structure or a physical limitation. Thus, it is unclear what the relationship between altering remodeling of chromatin and the interaction with a subunit of a chromatin of a chromatin remodeling complex is intended to be encompassed by the recitation of the phrase "altering remodeling of a chromatin." Clarification of the claim is requested.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a

gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: it is not apparent how a cell can comprise of an endogenous artificial zinc-finger. An artificial zinc finger would have to be inserted or transfected into a cell before it can structurally interact with a subunit of a chromatin-remodeling complex.

Claim 20 is objected to under MPEP 2173.05(h), as using improper Markush group language. The claim recites "or LKLF **or** BRCA2, or a zinc finger." The terminology "**or**" is unacceptable Markush group language when used several times in the same claim. The claim should recite "or" once before the last group mentioned.

Claims 2, 16, 28, 30, 32, 34, and 35, are vague and indefinite as to what the term "domain within in a protein" is intended to be encompassed with regard to interaction with a subunit of a chromatin of a chromatin remodeling complex. While a protein comprises of amino acids, it is not apparent what sequences of amino acids is required to define a domain within a protein. In the art of proteins, domains are usually defined by a structure or a physical limitation. Thus, it is unclear what the relationship between a domain and a protein is intended to be encompassed by the recitation of the term "domain within a protein." Clarification of the claim is requested.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is: a compound that modulates transcription in an in vitro system. The material required for the functionality of the system is not defined by the disclosure. Clarification is requested.

Claims 35-37 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a

gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships is how a domain within a protein with nucleic acid is structurally related to a method of altering remodeling of chromatin in a cell. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In view of the 112, second paragraph rejection of claim 30 because the structural limitation is indefinite, any in vitro system comprising a subunit of a chromatin remodeling complex and a portion of any protein anticipate the claim. Thus, the following rejections under 102 apply.

Claim 30 is rejected under 35 U.S.C. 102(a) as being anticipated by Haswell et al. (Molecular and Cellular Biology, Vol. 19, pp. 2817-2827, April 1999). Haswell teaches an in vitro system in which partially purified PHO5 mini-chromosome undergoes promoter chromatin remodeling (abstract). Furthermore, Haswell teaches that this in vitro system serves as a useful tool for identifying the components required for chromatin remodeling and for elucidating the mechanism by which PHO5 promoter chromatin structure is changed (abstract). In addition, Haswell teaches a subunit of a chromatin remodeling complex which the PHO5 mini-chromosome and a domain within a protein which is the transcription factor Pho4 (page 2819).

Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Orphanides et al. (Applicant's IDS, Cell, Vol. 92, pp. 106-116, 1998). Orphanides teaches an in vitro system comprising of a chromatin templates assembled in vitro and a transcription system composed of human general transcription factors and RNA polymerase II (abstract).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, Debbie Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1633
December 21, 2001

DAVE T. NGUYEN
PRIMARY EXAMINER